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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,062	02/17/2004	Thomas V. Magee	PC11895B	2483

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/781,062	Applicant(s) MAGEE ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8-10,13,14 and 17-22 is/are pending in the application.
 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,9,10,13 and 17-22 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>03 March 2006</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3 pages</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. According to a preliminary amendment filed on Feb. 17, 2004, the applicants have canceled claims 2-7, 11, 12, 15 and 16 and furthermore, have amended claim 1.
2. Claims 1, 8-10, 13, 14 and 17-22 are now pending in the application.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0)

where Y represents C and both B1 and B2 represent saturated or unsaturated carbocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 290.

II. Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0)

where Y represents N and both B1 and B2 represent saturated or unsaturated carbocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 544, subclass 333.

III. Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0)

where Y represents C and both B1 and B2 represent saturated or unsaturated heterocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 540, subclass 450.

IV. Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0)

where Y represents N and both B1 and B2 represent saturated or unsaturated heterocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 540, subclass 470.

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V. Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0)

where Y represents C, B1 represents saturated or unsaturated carbocyclic ring and B2 represents a saturated or unsaturated heterocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 255.

VI. Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0)

where Y represents N, B1 represents saturated or unsaturated carbocyclic ring and B2 represents a saturated or unsaturated heterocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 544, subclass 242.

VII. Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0)

where Y represents C, B1 represents a saturated or unsaturated heterocyclic ring and B2 represent saturated or unsaturated carbocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 268.1.

VIII. Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0)

where Y represents N, B1 represents a saturated or unsaturated heterocyclic ring and B2 represents a saturated or unsaturated carbocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 544, subclass 298.

4. The inventions I through IV as defined above are patentably distinct, each from the other since they are structurally so divergent that a reference showing compounds of

invention I would not render compounds of inventions II through VIII prima facie obvious. Search required for e.g; compounds of invention I in class 546, subclass 290 is not the same search required for e.g; compounds of invention II in class 544, subclass 333 and therefore, constitutes a burdensome search.

5. During a telephone conversation with the applicant's attorney, Mr. Phil Polster on March 3, 2006, a provisional election was made with traverse to prosecute the invention of group I, claims 1, 9, 10, 13, 14 and 17-22. Affirmation of this election must be made by applicant in replying to this Office action. Claim 8 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

7. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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9. Claims 18-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following eight different factors (see *Ex parte Foreman*, 230 USPQ at 547; *Wands*, *In re*, 858 F.2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, the state of the prior art, presence of working examples and the breadth of claims.

The instant compounds are inhibitors of PDE 4 isozyme and therefore, the instant compounds will have utility in treating only those disease conditions where structurally closely related PDE 4 inhibitors are well known in the prior art to have therapeutic utility. There is no teaching either in the specification or prior art regarding any disease condition which is solely mediated by PDE4 isozyme. There is no teaching either in the specification or prior art that PDE4 isozyme mediates all the disease conditions listed in instant claims 20 and 21 such as psoriasis, pulmonary hypertension, central nervous system disorders, liver injury, HIV etc. There is no guidance or direction provided in the

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specification that how the instant compounds having inhibitory effect on PDE4 isozyme will have utility in treating thousands of unrelated disease conditions listed in instant claims 20 and 21 either alone or in combination with hundreds of thousands of other drugs listed in instant claim 22. There are no working examples present showing efficacy of instant compounds alone or in combination with other any drug in known animal models thousands of disease conditions listed in instant claims 20 and 21. The instant compounds of formula (1.0.0) encompasses hundreds of thousands of compounds based on the values of variables w, B1, B2, R1-R6, A, RA, RB, RC, RD, k, j, n and m and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in known animal models of thousands of disease conditions listed in instant claims 20 and 21 using them alone or in combination with hundreds of thousands of other drugs and hence their utility in treating these disease conditions.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 17-19 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, page 4, first two line, the term ----indicates the point of attachment of each partial Formula (1.1.1) through (1.1.5)----- is indefinite since formulae (1.1.1), (1.1.2), (1.1.4) and (1.1.5) have been deleted by amendment.

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In claim 17, page 18, second compound from bottom, the term ---of formula --- is indefinite since there is no formula present.

In claims 18 and 19, the term ---mediated by the PDE4 isozyme--- is indefinite since specific disease conditions are not mentioned. In claim 22, the term ---combination --- is vague and indefinite since the purpose of the combination is not clear. Is the combination directed to a method of specific treatment?

Claim 19 provides for the use of pharmaceutical composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claim 19 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 9, 10, 13 and 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Marfat (WO 98/45268, cited on applicant's form 1449).

Marfat discloses nicotinamides as inhibitors of PDE4 isozyme, pharmaceutical compositions containing these compounds and a method of treating various disease conditions using these compounds. The compounds disclosed in examples 229 and 285 by Marfat anticipate the instant claims when j is 1, R3 is H, n is 1, w is O, B1 is phenyl and B2 represents either a phenyl group or a cyclohexyl group in the instant compounds of formula (1.0.0).

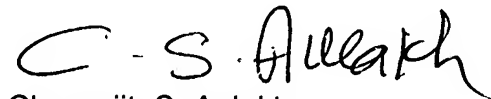
16. Claims 1, 9, 10, 13, 14 and 17-22 are objected for containing non-elected subject matter.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "C. S. Aulakh".

Charanjit S. Aulakh
Primary Examiner
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